REMARKS

The claims of the application previously acted on by the Office Action have been duly reconsidered, and all claims have been cancelled in favor of new claims 52 to 65. Of these new claims, claims 52 to 58 are method claims for treating an eye of a mammal with a polyaphron gel, and claims 59 to 65 are claims to a polyaphron gel. In drafting the new claims, the comments of the Examiner were very carefully considered.

The method claims 52 to 58 define the present invention in clear distinct terms and particularly point the novelty and unobviousness of the present invention. Claim 52 is reproduced below:

> 52. (new) Method for the treatment of an eye of a mammal, the eye having a conjunctival sac comprising the steps of:
>
> c. preparing a sterile polyaphron gel comprising at least one water-soluble fluorinated surfactant in a concentration lower than critical micellae formation, water and one homopolar component in an amount greater than 60% by weight selected from the group consisting of partially fluorinated fluorocarbon compounds of the general formula R_FR_H, $R_FR_HR_F$, fluorocarbon oligomers of the type $(R_F)_XR_H$, silicone oil, and mixtures thereof;
>
> d. introducing the sterile polyaphron gel into the conjunctival sac of the eye to form a gel-like reservoir whereupon at each blink of the eye, a portion of the sterile polyaphron gel irreversibly liquefies under the effect of the shear forces caused by the blink, extrudes from the conjunctival sac and spreads over the cornea of the eye as a thin liquid film functioning as a tear substitute.

As recited in claim 52, the essence of the invention in plain terms is the use of novel polyaphron gel, prepared as described and claimed, that is introduced into the conjunctival sac of the eye of a mammal. The polyaphron gel has the property of being converted **irreversibly** to the liquid state when subjected to shear stress, whereupon, by being stored in the conjunctival sac of the eye, portions are blinked out, irreversibly converted to liquid and spread over the cornea of the eye as thin liquid films functioning

as a tear substitute. This is entirely novel and not anticipate or rendered unobvious by the cited prior art.

More particularly, Riess et al Patent No. 5573757, which was cited as anticipatory over the cancelled claims, discloses a highly viscoelastic gel (col 3, ln 67) composed of an oily phase containing at least one linear, branched, or cyclic fluorinated hydrocarbon compound, an aqueous phase and at least one surfactant representing from about 0.1 to 10% of the composition (col 4, ln 11-43). The gel is defined (col 4, ln 28-29) as a semi-solid, apparently homogenous substance, which can have the consistency of gelatin. The gel is used mainly as a protective transparent cream to treat burns. Nothing is said in the specification of this patent concerning the properties of the gel vis-à-vis shear stress. The gel is intended to be used in its gel form as the base for whatever composition is to be applied to the skin.

The other cited and applied reference, Meadows Patent No. 5480914 discloses a non-aqueous thixotropic drug delivery suspension and method of use, composed of a suspending aid dispersed in a fluorinated liquid carrier. The thixotropic composition (relatively viscous or gelatinous) becomes less thixotropic when shaken to impose a shearing force on the composition for drop instillation. However, it is stated quite clearly (col 4, ln 51-54) that

> "Following administration to the target site and removal of the dropping or delivery stress, the thixotropic compositions rapidly return to their original higher or "at rest" viscosities."

From the foregoing, it is readily apparent that neither reference discloses a polyaphron gel having the claimed properties, namely, irreversibly liquefying under shear stress, and therefore, neither provides any suggestion, let alone a teaching, of preparing a polyaphron gel of the claimed composition and introducing it into the conjunctival sac of the eye so that a portion of the polyaphron gel will be extruded from the conjunctival sac at each blink of the eye and irreversibly liquefy under the shear stress of the blink, and

spread out over the cornea of the eye as a thin liquid film functioning as a tear substitute. See the claim limitations in claim 52 above.

In Reiss et al, the gel disclosed is a highly viscoelastic gel, but there is no disclosure of what happens to the gel under shear stress, if anything. Its properties in this regard are not mentioned. In Meadows, the thixotropic suspension is not disclosed as a gel, and under shear stress it liquefies reversibly, i.e. returns to its thixotropic state when at rest. This would be self defeating if one tried to use this suspension as a tear substitute. The purpose and function of the Meadows suspension is solely as a drug delivery vehicle. Neither of the references relied upon meet the limitations of claim 52 and the claims dependent thereon. Accordingly, claims 52 to 58 are patentably distinguished over the cited and applied prior art.

Claims 59 to 65 are claims, directed to a novel polyaphron gel with the properties claimed regarding the capability to liquefy irreversibly under shear stress. Also, critical to the polyaphron gel is the limitation in claim 59 regarding the water-soluble fluorinated surfactant being in a concentration lower than critical micellae formation. This criticality is not disclosed in Reiss et al, wherein the concentration for the surfactant is given as from about 0.1% to 10%. Nor does Reiss et al disclose a polyaphron gel as claimed. Most importantly, Reiss et al is silent regarding the properties of their gel under shear stress, and allege no benefit therefrom. The present invention in claim 59, claims

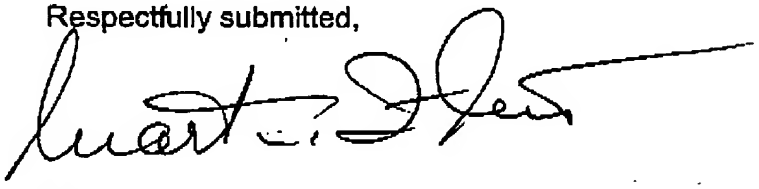
> "a sterile polyaphron gel that is adapted for introduction into the conjunctival sac of an eye of a mammal to form a gel-like reservoir whereupon at each blink of the eye, a portion of the sterile polyaphron gel will liquefy irreversibly under the effect of the shear forces caused by the blink, extrude from the conjunctival sac and spread over the cornea of the eye as a thin liquid film functioning as a tear substitute."

This property distinguishes the polyaphron gel of the present invention, as claimed, from the gel compositions disclosed by Reiss et al, which does not have this property. As mentioned above, Meadows does not show a gel, but only a thixotropic suspension that will become less viscous under shear stress, but which returns to its "at rest" condition to its original higher viscosity.

In light of the foregoing remarks, this application should be in condition for allowance, and early passage of this case to issue is respectfully requested. If there are any questions regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

It is respectfully requested that, if necessary to effect a timely response, this paper be considered as a Petition for an Extension of Time, time sufficient, to effect a timely response, and shortages in this or other fees, be charged, or any overpayment in fees be credited, to the Deposit Account of the undersigned, Account No. 500601 (Docket no. 754-X01-004)

Respectfully submitted,



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